SUBSTITUTE SENATE BILL 6241

State of Washington 60th Legislature 2008 Regular Session

By Senate Health & Long-Term Care (originally sponsored by Senators Fairley, Pflug, Kohl-Welles, Kline, and Franklin)

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1 AN ACT Relating to prohibiting the sale and use of 2 prescriber-identifiable prescription data for marketing or promotional 3 purposes; amending RCW 42.56.350; adding a new chapter to Title 19 RCW; creating a new section; and prescribing penalties. 4

5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

- 6 <u>NEW SECTION.</u> **Sec. 1.** (1) The legislature finds that:
 - (a) The state of Washington has clear and long-standing interests in maximizing the health and well-being of its residents, maintaining practice standards in the licensed professions, safeguarding the confidentiality and integrity of the doctor-patient relationship, combating undue influence of marketing on health care choices, and containing health care costs;
 - (b) To further its substantial interest in the health and well-being of its residents and in containing health care costs, the state of Washington has shown a strong commitment to evidence-based care and cost-effective health purchasing. Washington state has been most active in this regard with respect to prescription drug purchasing focused on clinical and cost-effectiveness, including the Washington evidence-based prescription drug program and the state preferred drug

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list under RCW 70.14.050, the prescription drug purchasing consortium under RCW 70.14.060, and both generic and therapeutic drug substitution under chapter 69.41 RCW. In addition, the medicaid program is engaged in numerous efforts to improve the quality of, and reduce variability in, prescribing of pain management and mental health medications. The state also aggressively seeks supplemental rebates to lower drug costs in the medicaid program. The Washington state health technology assessment program, established under chapter 70.14 RCW, is applying the principles of evidence-based care and cost-effective purchasing to the review of medical devices and procedures for state purchased health care programs. Finally, the state is an active participant in the Puget Sound health alliance, whose goal is to improve the quality and transparency of health services provided across the public and private sectors;

- (c) Prescriber-identifiable prescription data shows details of prescribers' drug use patterns. Using this data, pharmaceutical manufacturers can track the responses of prescribers to their marketing campaigns and use that information to tailor positive and negative reinforcements, including gifts, invitations to special events, paid speaking and consulting opportunities, prestigious board appointments, messages of appreciation or disappointment, and specially tailored marketing messages, that are intended to, and do in fact, exert an undue influence over prescribing practices;
- (d) Numerous studies have shown that direct-to-physician marketing of prescription drugs raises prescribing costs and leads to more rapid prescribing of new drugs and decreased use of older or generic medications that may be more effective according to the best available medical evidence. These negative effects of direct-to-prescriber marketing are aggravated by marketer access to prescriber-identifiable prescription data;
- (e) Health care providers in Washington who write prescriptions for their patients have a strong interest in the integrity of the patient-provider relationship and a reasonable expectation that the information in their prescriptions, including their own identity, will not be used for purposes other than the filling and processing of the payment for that prescription. The Washington chapter of the academy of family practice, the Washington chapter of the academy of pediatrics, and the

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Washington state medical association support a prohibition on the sale or use of individual prescriber prescription data for marketing or promotional purposes;

- (f) The removal of the names and addresses of patients from prescription drug data purchased by pharmaceutical manufacturers does not completely protect the privacy of patients. Tracking treatment history and prescriber identity can allow reidentification of patients. Even with patient identities removed, specific patients and shifts in their prescription drug use can be tracked by assigning individual identification numbers to patients, thus enabling marketing directed at convincing a prescriber to change a particular patient's treatment without the patient's knowledge or consent;
- (g) The physician data restriction program offered by the American medical association is not an adequate remedy for Washington physicians, because (i) many physicians do not know about the program; (ii) many physicians do not receive the end-of-period notification for renewing or canceling their participation; (iii) under the program, physician-specific prescribing data can still be sold to data mining companies even though it is not supposed to be provided to sales representatives; (iv) the American medical association could choose to end the program at any time; and (v) the American medical association has a conflict of interest in operating the program because it earns over forty million dollars per year by selling physician identifying information to companies that match the identifying information to prescription drug claims;
- (h) It is estimated that the pharmaceutical industry spends between thirty billion dollars and fifty-four billion dollars annually on marketing pharmaceuticals in the United States. Marketing programs are designed to increase sales, income, and profit. Between eighty and ninety percent of pharmaceutical marketing budgets are directed at physicians and other prescribers. Progress toward these goals can come at the expense of evidence-based care, efforts to contain health care costs, and sometimes the health of individual patients;
- (i) Newer drugs on the market do not necessarily provide additional benefits over older drugs but do add costs and as yet unknown side effects. Marketing that results in prescribers using the newest drugs results in prescribing drugs that are more likely to be subject to

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federal food and drug administration "black box" warnings or withdrawal from the market for safety reasons; and

- (j) The sale of prescriber-identifiable prescription data runs counter to Washington's strong commitment to both evidence-based care and cost-effective health purchasing. Pharmaceutical marketers, through their surveillance of prescription records that include prescriber-identifiable data, are able to monitor and reward prescribing practices that favor the financial interests of pharmaceutical manufacturers over the interests of patients in clinically effective and cost-effective care. This act is necessary to realize the goals of the programs and activities undertaken by the state of Washington to implement evidence-based care and cost-effective health purchasing and to preserve the integrity of the patient-prescriber relationship.
- (2) It is the intent of the legislature to improve the quality of health care received by Washingtonians, further health care cost containment, promote professional standards in the licensed professions, protect the confidentiality of prescribing information, safeguard the integrity of the doctor-patient relationship, and restrain undue influence over prescribing decisions by prohibiting conduct involving the sale, disclosure, and use of individual prescriber prescription data for marketing or promotional purposes.
- NEW SECTION. Sec. 2. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.
- 25 (1) "Health care provider" has the same meaning as in RCW 48.43.005(16).
 - (2) "Health carrier" has the same meaning as in RCW 48.43.005(18).
 - (3) "Marketing" or "market" includes advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence the prescribing behavior of an individual health care provider to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.
- 35 (4) "Person" includes a natural person, corporation, limited 36 liability company, trust, unincorporated association, partnership, and 37 any other type of entity.

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- 1 (5) "Pharmacy" means any individual or entity licensed under 2 chapter 18.64 RCW.
 - (6) "Prescriber" means a health care provider authorized by law to prescribe and administer prescription drugs in the course of professional practice.
 - (7) "Promotion" or "promote" means any activity or product the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement, poster, free sample, detailing visit, or personal appearance.
- 10 (8) "Regulated records" means information or documentation from a 11 prescription written by a prescriber doing business in Washington or a 12 prescription dispensed in Washington.
- NEW SECTION. Sec. 3. (1) No person shall knowingly sell, disclose, or use regulated records that include prescriber-identifiable data to market or promote a prescription drug.
 - (2) This section does not restrict the sale, disclosure, or use of regulated records that include prescriber-identifiable data for the purposes of:
 - (a) Activities related to filling a valid prescription, including the dispensing of prescription medications to a patient or to the patient's authorized representative; the transmission of prescription information between an authorized prescriber and a pharmacy; the transfer of prescription information between pharmacies; the transfer of prescription records that may occur if pharmacy ownership is changed or transferred; and pharmacy reimbursement;
 - (b) Formulary compliance;

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- (c) Care management related to the diagnosis, treatment, or management of illness for a specific patient, including care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy, or other information about the drug being dispensed, treatment options, or clinical trials;
- (d) Care management related to specialty pharmacy care for conditions including, but not limited to, hemophilia, pulmonary arterial hypertension, multiple sclerosis, respiratory syncytial virus, and hormone growth deficiencies;

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1 (e) Utilization review by a health care provider, the patient's 2 health carrier, or an agent of the provider or carrier;

- (f) Health care research and statistical reports resulting from such research, including, but not limited to, postmarketing surveillance research, drug interaction research, drug safety studies, and population-based public health research;
- (g) Collection and analysis of prescription drug utilization data for health care quality improvement purposes, including development of evidence-based treatment guidelines or health care performance effectiveness and efficiency measures, promoting compliance with evidence-based treatment guidelines or health care performance measures, and providing prescribers with information that details their practices relative to their peers to encourage prescribing consistent with evidence-based practice;
- (h) Collection and dissemination of drug utilization data to promote transparency in evaluating performance related to the health care quality improvement measures included in (g) of this subsection;
- (i) The transfer of prescription drug utilization data to and through secure electronic health record or personal health record systems;
- (j) Alerting prescribers about a prescription drug recall, change in labeling information, or any purpose authorized by the federal food and drug administration or other federal or state government regulatory authority;
- (k) The collection and transmission of prescription information to a Washington or federal law enforcement officer engaged in his or her official duties as otherwise provided by law;
- (1) The collection and transmission of prescription information to any government agency or government agency-sponsored program to carry out its duties, or to any private person acting on behalf of a federal, state, or local agency to carry out its duties;
- (m) The collection and transmission of prescription drug information in connection with any civil, criminal, administrative, or other proceeding before any federal, state, or local court or administrative agency or before any self-regulatory body, including the service of process, investigation in anticipation of litigation, and the execution or enforcement of judgments and orders, or pursuant to an order of a federal or state court; or

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(n) As otherwise expressly provided by law.

- (3) This section does not prohibit the sale, disclosure, or use of regulated records for marketing or promotion, organized by medical specialty or otherwise, if the data does not identify a prescriber, and there is no reasonable basis to believe that the data provided could be used to identify a prescriber or a patient.
- (4) Any person that has received regulated records that include prescriber-identifiable data under subsection (2) or (3) of this section may reuse, resell, or redisclose that information only for purposes authorized under those subsections. If the information is reused, resold, or redisclosed, the person or entity must maintain records identifying each person or entity that has received information and the permitted purpose for which the information has been used. The records must be maintained for a period of five years following the date or reuse, resale, or redisclosure, and must be made available to any person upon request.
- <u>NEW SECTION.</u> **Sec. 4.** Any person who knowingly fails to comply with the requirements of this chapter or rules adopted pursuant to this chapter by selling, using, or disclosing regulated data in a manner not authorized by this chapter or its rules shall be subject to an administrative penalty of not more than fifty thousand dollars per violation, as assessed by the secretary of the department of health. The office of the attorney general shall take necessary action to enforce payment of penalties assessed under this section.
- NEW SECTION. Sec. 5. In addition to any other remedy provided by law, the legislature finds that the practices covered by this chapter are matters vitally affecting the public interest for the purpose of applying the consumer protection act, chapter 19.86 RCW. A violation of this chapter is not reasonable in relation to the development and preservation of business and is an unfair or deceptive act in trade or commerce and an unfair method of competition for the purpose of applying the consumer protection act, chapter 19.86 RCW.
- **Sec. 6.** RCW 42.56.350 and 2005 c 274 s 415 are each amended to read as follows:
 - (1) The federal Social Security number of individuals governed

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under chapter 18.130 RCW maintained in the files of the department of health is exempt from disclosure under this chapter. The exemption in this section does not apply to requests made directly to the department from federal, state, and local agencies of government, and national and state licensing, credentialing, investigatory, disciplinary, and examination organizations.

- (2) The current residential address and current residential telephone number of a health care provider governed under chapter 18.130 RCW maintained in the files of the department are exempt from disclosure under this chapter, if the provider requests that this information be withheld from public inspection and copying, and provides to the department of health an accurate alternate or business address and business telephone number. The current residential address and residential telephone number of a health care provider governed under RCW 18.130.040 maintained in the files of the department of health shall automatically be withheld from public inspection and copying unless the provider specifically requests the information be released, and except as provided for under RCW 42.56.070(9).
- 19 (3) Records held by an agency administering a state purchased
 20 health care program, as defined in RCW 41.05.011(2), that include
 21 prescription information containing prescriber-identifiable data that
 22 could be used to identify a prescriber, are exempt from disclosure
 23 under this chapter, except that the records shall be made available
 24 upon request for the purposes expressed in section 3(2) of this act.
- NEW SECTION. Sec. 7. Sections 1 through 5 of this act constitute a new chapter in Title 19 RCW.
- NEW SECTION. Sec. 8. This act may be known and cited as the prescription privacy and integrity act of 2008.

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